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United States Environmental Protection Agency

Webinar Workshop to Review Initial Draft Materials for the Ozone Integrated Science Assessment (ISA) for Health and Welfare Effects
Orientation and Introduction
October 23 & 24, 2018

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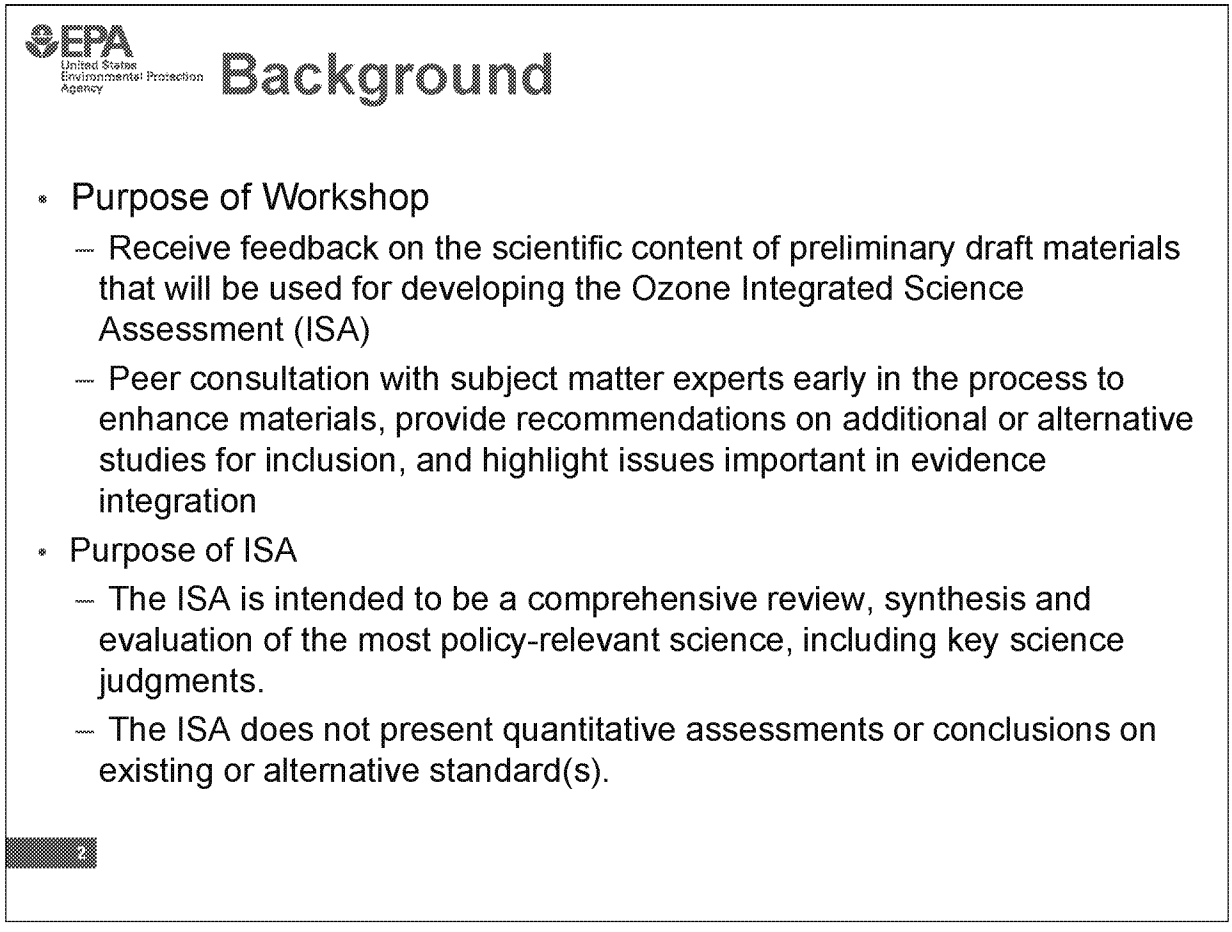

We do recognize that these preliminary draft materials are in many places not fully developed. However, we believe this is the perfect opportunity to check in with external experts to determine where there are deficiencies, obtain thoughts on how to structure some content, and identify potential approaches to thoroughly integrate evidence across disciplines. This is why we value your comments and feedback so much during the following webinars.

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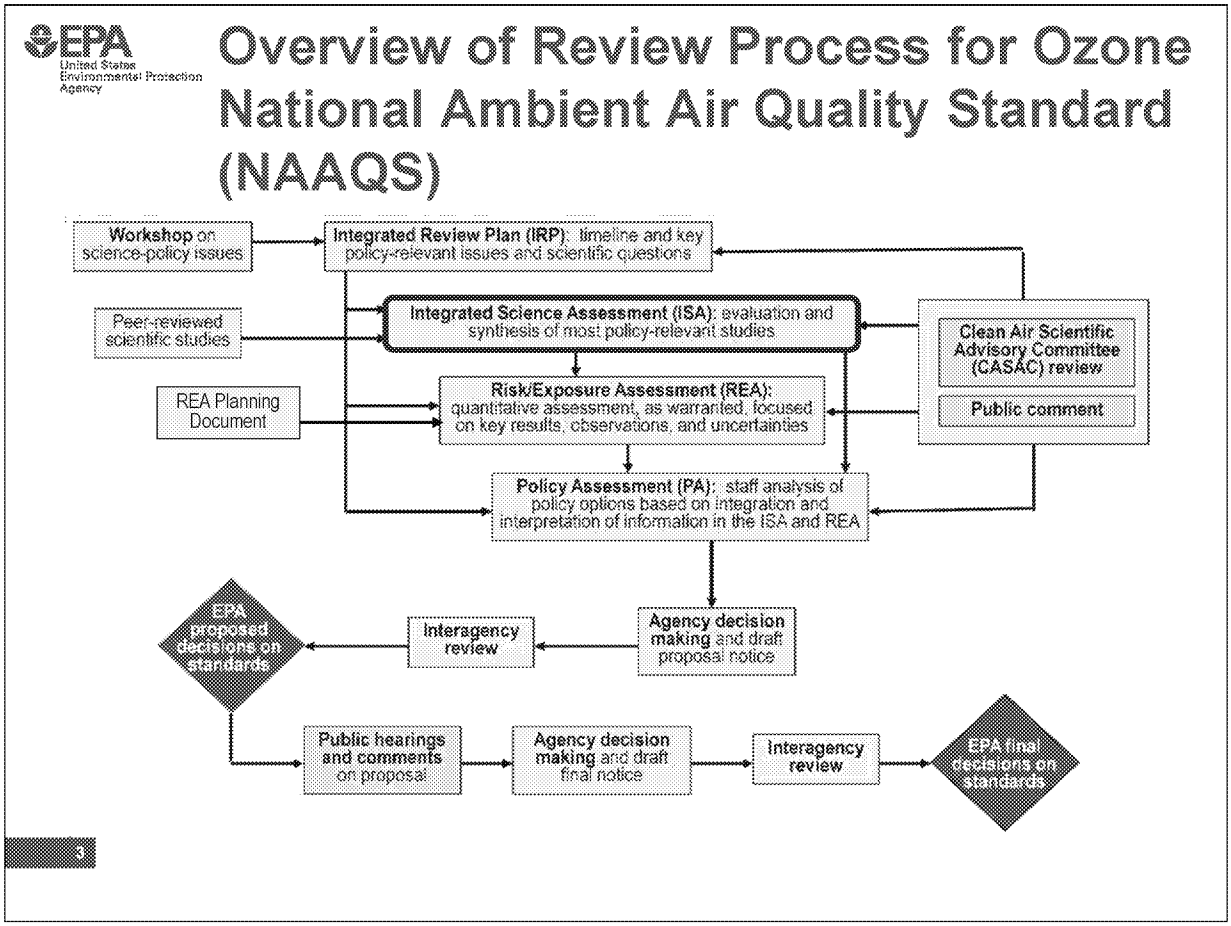

No science-policy workshop for this expedited review, Call for Information was published in Federal Register in June 2018. The information we gathered from the Call for Information helped frame the policy-relevant questions we pose in the Integrated Review Plan (IRP) for the ISA and the content in the preliminary materials.

In the next week or so we plan to release the Ozone IRP; a call with the Charter CASAC panel is scheduled for the end of November.

Deliberative Process / Ex. 5

Overview of Current Ozone NAAQS

Current Standards					Decisions in 2015 Review
Indicator	Averaging Time	Primary/Secondary	Level	Form	
O_3	8-hour	Primary (health) and Secondary (welfare*)	0.070 ppm	Annual fourth-highest daily maximum 8 hour average concentration, averaged over 3 years	Revised from 0.075 ppm

* Under Clean Air Act, section 302(h) (42 U.S.C. § 7602(h)), effects on welfare include, but are not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

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Anticipated Timeline for Ozone ISA

Major Milestone	Projected Target Dates
First draft ISA	Spring 2019
CASAC/public review of draft ISA	Summer 2019
Final ISA	Spring 2020

General Outline for Ozone ISA

- **Preamble** (online): Process of ISA development; framework for causality determinations; public health impact; concepts in evaluating adversity of health and welfare effects
- **Preface**: Legislative requirements; history of ozone NAAQS review
- **Executive Summary**
- **Integrative Synthesis**: Summary with emphasis on policy-relevant issues
- **Appendices**:
  - Appendix 1: Atmospheric Concentrations and Trends
  - Appendix 2: Exposure to Ambient zone
  - Appendix 3: Health Effects-Respiratory
  - Appendix 4: Health Effects- Cardiovascular
  - Appendix 5: Health Effects-Mortality
  - Appendix 6: Health Effects-Other Health Endpoints
  - Appendix 7: Ozone Effects on Vegetation and Ecosystems
  - Appendix 8: Role of Tropospheric Ozone on Climate

Health and welfare appendices contain integration of evidence across outcomes and scientific disciplines; also contain causality determinations

Scope of Ozone ISA

The ISA is tasked with answering the question "Is there an independent effect of ozone on health and welfare at relevant ambient concentrations?"

- Builds on conclusions made in previous assessments (not encyclopedic)
- Contains evidence from peer-reviewed literature

The timeline is must faster than in the past and this ISA is being developed with new efficiencies.

- Automated tools for literature search and screen
- Information conveyed through bullets and tables
- PECOS statements to narrow scope

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The scope is detailed in the IRP and we will ask CASAC for their opinion on the adequacy of this scope in evaluating the collective body of health and welfare effects evidence for ozone next month.

PECOS Statements

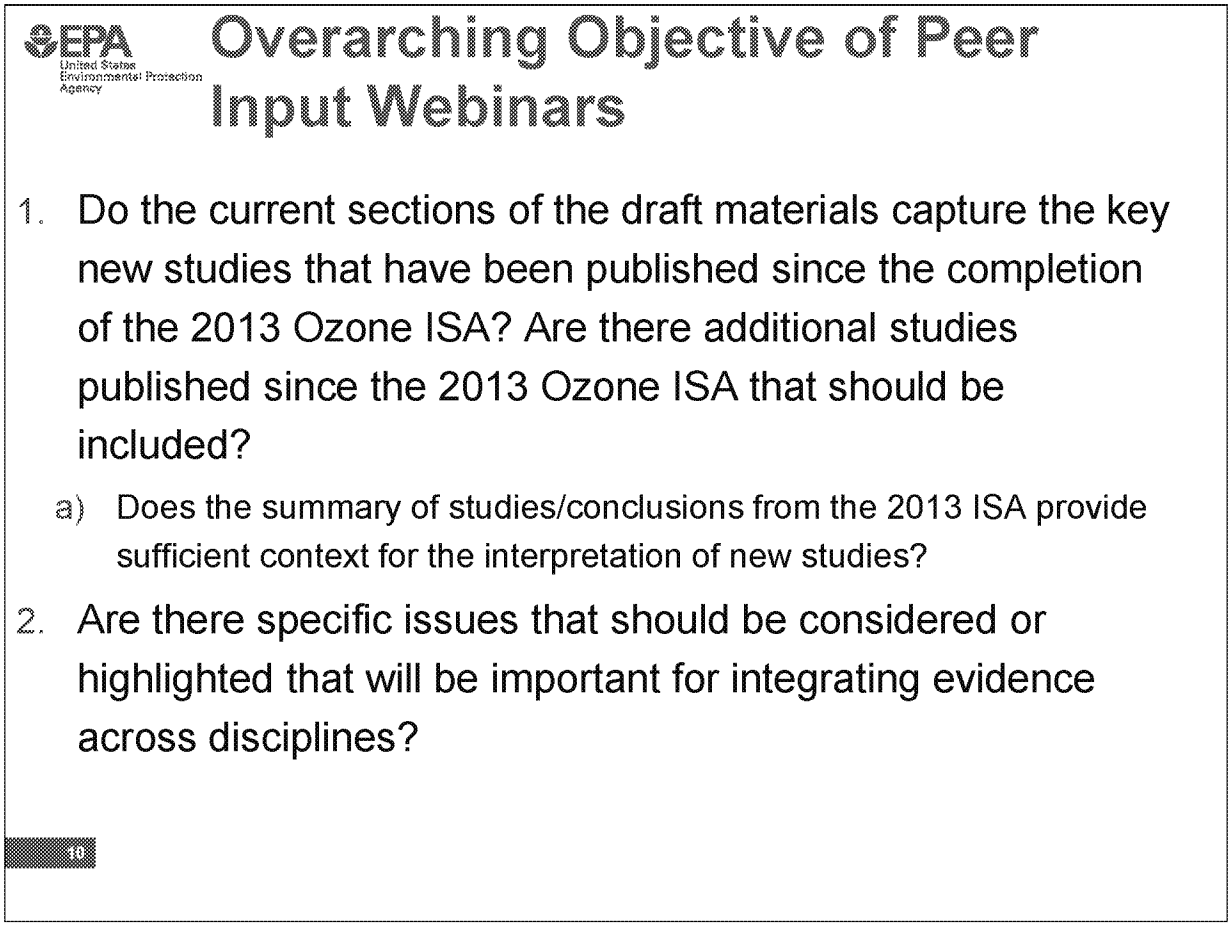
Used to define parameters and serve as guides for:

- literature search strategy
- criteria for inclusion/exclusion
- type of data extracted
- integration
- synthesis of results

P = Population
E = Exposure
C = Comparison
O = Outcome
S = Study Design

PECOS- Example (Experimental)

Exposure Duration and Health Effect	Population, Exposure, Comparison, Outcome, Study Design (PECOS) Statements
Short-term exposure and respiratory, cardiovascular, metabolic, nervous system, reproductive or developmental effects	Among the study population of any controlled human exposure or animal toxicological study of mammals at any lifestage (P), of interest are the studies of the relationship between short-term (in the order of minutes to weeks) inhalation exposure to relevant O_3 concentrations (i.e., 0.4 ppm or below for humans, 2 ppm or below for other mammals) (E) and respiratory, cardiovascular, metabolic, nervous system, reproductive or developmental effects (O) when human subjects serve as their own controls with an appropriate washout period or when comparison to a reference population exposed to lower levels is available, or, in toxicological studies of mammals, an appropriate comparison group is exposed to a negative control (i.e., clean air or filtered air control) (C).
Long-term exposure and respiratory, cardiovascular, metabolic, nervous system, carcinogenic, reproductive or developmental effects	Among the study population of any animal toxicological study of mammals at any lifestage (P), of interest are the studies of the relationship between long-term (in the order of months to years) inhalation exposure to relevant O_3 concentrations (i.e., 2 ppm or below) (E) and respiratory, cardiovascular, metabolic or nervous system, carcinogenic, reproductive or developmental effects (O) when an appropriate comparison group is exposed to a negative control (i.e., clean air or filtered air control) (C).



The questions panelists were provided to guide their review will be presented during each session. For some sessions staff developed additional questions that came to fruition while preparing for the webinars. Depending on the course of the discussion panelists may be asked to provide their thoughts on these additional questions.

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Peer Input Expert Reviewers

Topic	Date	Reviewers
Eco/ Welfare	Monday October 29, 2018	Elizabeth Ainsworth (USDA, University of Illinois) Michael Bell (US NPS) Kent Burkey (USDA/ NCSU) John Couture (Purdue University)
Epi/Exposure	Wednesday October 31, 2018	James Crooks (National Jewish Health) James Gauderman (Keck School of Medicine at USC) Kaz Ito (NYC Department of Health) Elizabeth Mannshardt (EPA, NCSU) Melinda Power (The George Washington University) Matthew Strickland (University of Nevada-Reno) Jennifer Weuve (Boston University)
Tox/ Experimental	Thursday November 1, 2018	Alex Carll (University of Louisville) Mehdi Hazari (EPA) Travis Knuckles (West Virginia University) Urmila Kodavanti (EPA) David Peden (UNC-Chapel Hill) Edward Schelegle (University of California-Davis)
Atmospheric/ Background/ Climate	Monday November 5, 2018	Arlene Fiore (Columbia University) Daniel Jaffe (University of Washington-Bothell) Terry Keating (EPA) Andrew Langford (NOAA) Loretta Mickley (Harvard University) David Parrish (University of California-Davis) Ted Russell (Georgia Tech)

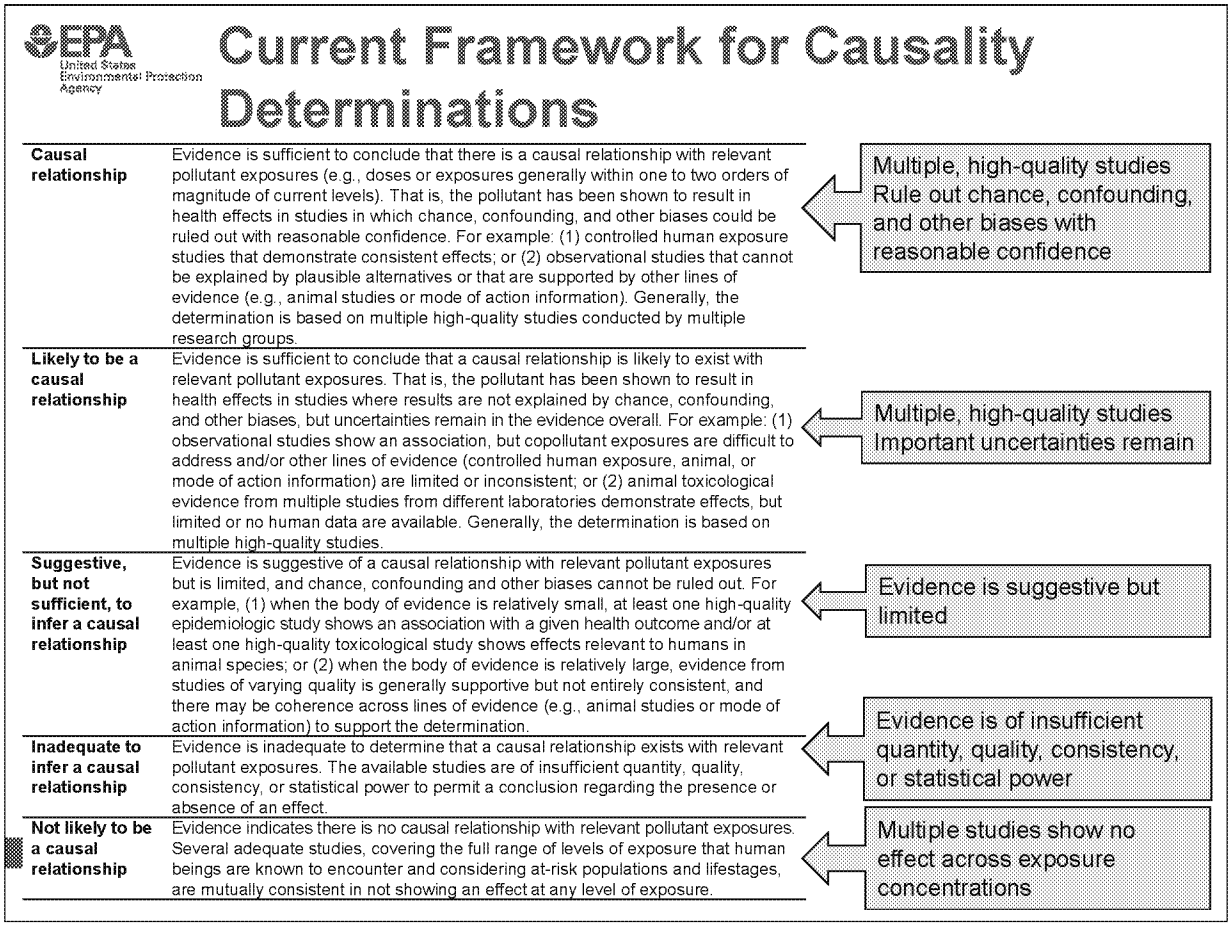
Webinar Logistics

- Pre-webinar comments due one week before webinar; revise after webinar and resubmit to ICF
- Agenda/timing
- Role of Lead Discussant
- Role of EPA staff
- Role of ICF

After Peer Input Webinars

Next Steps for NCEA

- Further develop preliminary materials, considering comments
- Develop conclusions and make causality determinations
- Draft Integrative Synthesis and Executive Summary



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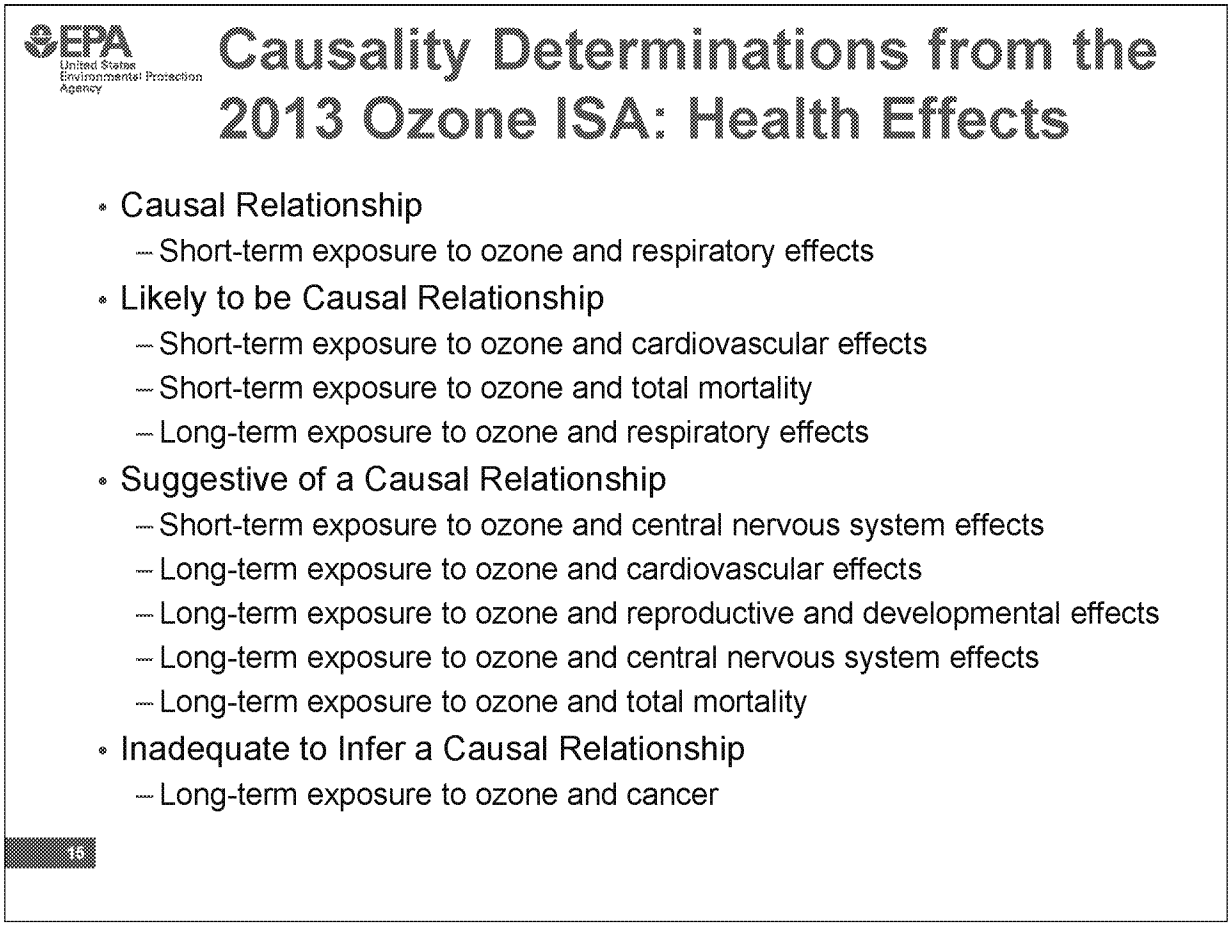
After these series of webinars we will continue to work on draft materials and move towards integrating the evidence across disciplines and making causality determinations. For those of you unfamiliar with our process of making causality determinations, we thought it would be beneficial to highlight our weight-of-evidence framework that is used to form the overall conclusions of the ISA. We use a 5-level hierarchy. The delineation between each level is based on our ability to rule out with reasonable confidence chance, confounding and other biases. Additionally we take into consideration doses and exposure concentrations along with the overall quality of the studies evaluated. It is important to note that in evaluating the overall weight of evidence we are also assessing consistency of effects within a discipline, the coherence of effects across disciplines, and biological plausibility.



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The next few slides are going to highlight our causality determinations for health and welfare effects from the 2013 ISA to provide a basis for where things stand leading into this review.

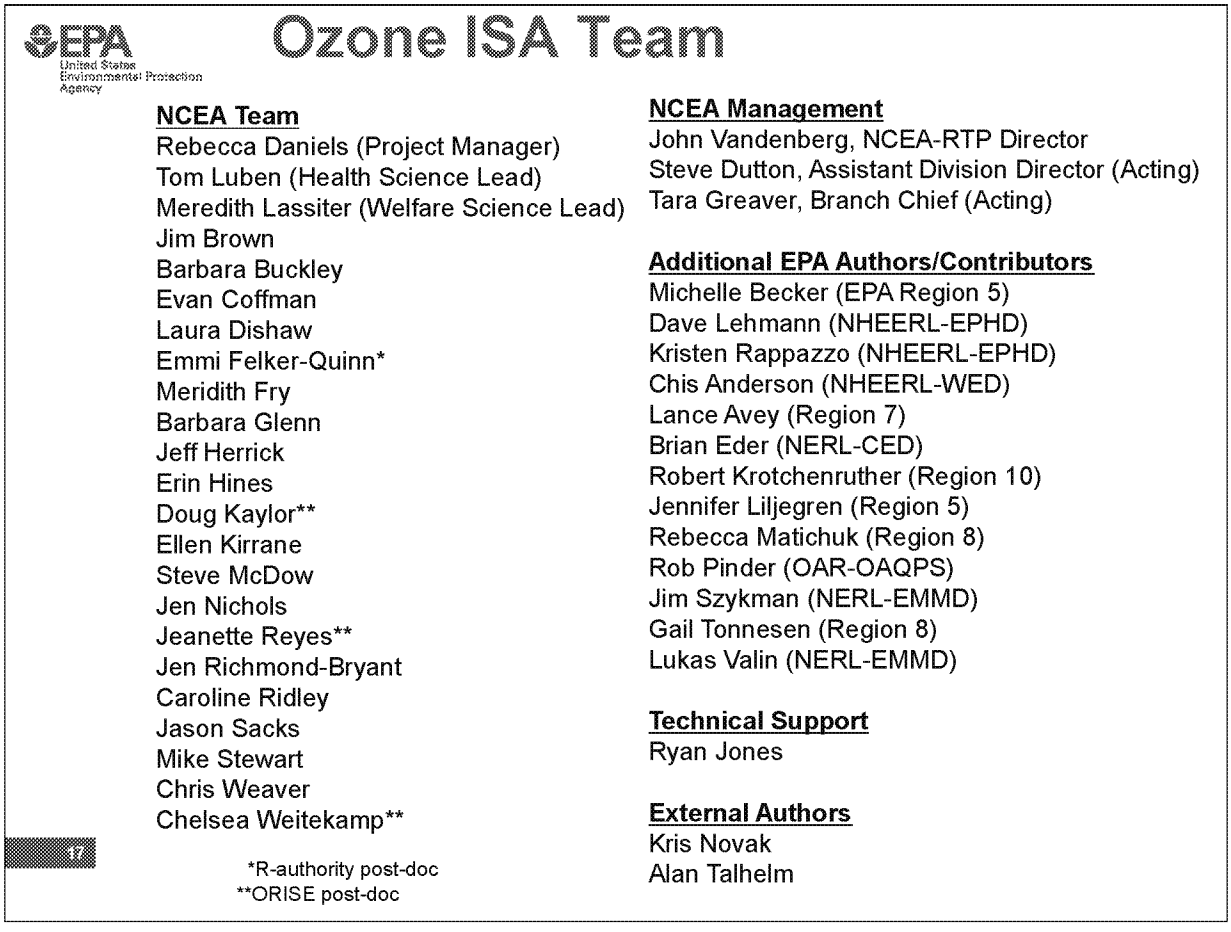
Causality Determinations from the 2013 Ozone ISA: Welfare Effects

Vegetation and Ecosystem Effects

- Causal Relationship
  - Visible Foliar Injury Effects on Vegetation
  - Reduced Vegetation Growth
  - Reduced Productivity in Terrestrial Ecosystems
  - Reduced Yield and Quality of Agricultural Crops
  - Alteration of Belowground Biogeochemical Cycles
- Likely to be Causal Relationship
  - Reduced Carbon Sequestration in Terrestrial Ecosystems
  - Alteration of Terrestrial Ecosystem Water Cycling
  - Alteration of Terrestrial Community Composition

Effects on Climate

- Causal Relationship
  - Radiative Forcing
- Likely to be Causal Relationship
  - Climate Change



I'd first like to recognize our large and diverse team, with expertise spanning all of the scientific disciplines. In addition to our internal authors we had a large number of external authors that helped us in developing these preliminary draft materials. We are extremely grateful for their contributions to these materials.

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Questions?

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All PECOS Statements

Experimental Studies

Exposure Duration and Health Effect	Population, Exposure, Comparison, Outcome, Study Design (PECOS) Statements
Short-term exposure and respiratory, cardiovascular, metabolic, nervous system, reproductive or developmental effects	Among the study population of any controlled human exposure or animal toxicological study of mammals at any lifestage **(P),** of interest are the studies of the relationship between short-term (in the order of minutes to weeks) inhalation exposure to relevant O_3 concentrations (i.e., 0.4 ppm or below for humans, 2 ppm or below for other mammals) **(E)** and respiratory, cardiovascular, metabolic, nervous system, reproductive or developmental effects **(O)** when human subjects serve as their own controls with an appropriate washout period or when comparison to a reference population exposed to lower levels is available, or, in toxicological studies of mammals, an appropriate comparison group is exposed to a negative control (i.e., clean air or filtered air control) **(C).**
Long-term exposure and respiratory, cardiovascular, metabolic, nervous system, carcinogenic, reproductive or developmental effects	Among the study population of any animal toxicological study of mammals at any lifestage **(P),** of interest are the studies of the relationship between long-term (in the order of months to years) inhalation exposure to relevant O_3 concentrations (i.e., 2 ppm or below) **(E)** and respiratory, cardiovascular, metabolic or nervous system, carcinogenic, reproductive or developmental effects **(O)** when an appropriate comparison group is exposed to a negative control (i.e., clean air or filtered air control) **(C).**

Epidemiologic Studies

Exposure Duration and Health Effect	Population, Exposure, Comparison, Outcome, Study Design (PECOS) Statements
Short-term exposure and respiratory effects	In any U.S. or Canadian population, including populations or lifestages that might be at increased risk **(P)**, of interest is the change in risk (incidence/prevalence) of respiratory effects **(O)** per unit increase **(C)** in ppb of *short-term* ambient concentration of O_3 **(E)**, observed in studies relevant for the health outcome and exposure duration of interest **(S).** Also of interest is the lowest concentration that produces a measurable change in risk.
Short-term exposure and mortality; long-term exposure and respiratory effects	In any U.S. or Canadian population, including populations or lifestages that might be at increased risk **(P)**, of interest is the change in risk (incidence) of mortality **(O)** per unit increase **(C)** in ppb of *short-term* ambient concentration of O_3 **(E)**, observed in studies relevant for the health outcome and exposure duration of interest **(S).** Also of interest is the lowest concentration that produces a measurable change in risk. In any U.S. or Canadian population, including populations or lifestages that might be at increased risk **(P)**, of interest is the change in risk (incidence/prevalence) of respiratory effects **(O)** per unit increase **(C)** in ppb of *long-term* ambient concentration of O_3 **(E)**, observed in studies relevant for the health outcome and exposure duration of interest **(S)**. Also of interest is the lowest concentration that produces a measurable change in risk.
Short-term exposure and cardiovascular effects	In any U.S., Canadian, European or Australian population, including populations or lifestages that might be at increased risk **(P)**, of interest is the change in risk (incidence/prevalence) of cardiovascular effects **(O)** per unit increase **(C)** in ppb of *short-term* ambient concentration of O_3 **(E)**, observed in studies relevant for the health outcome and exposure duration of interest **(S)**. Also of interest is the lowest concentration that produces a measurable change in risk.
Short-term exposure and nervous system effects; long-term exposure and cardiovascular, nervous system, reproductive or developmental effects, cancer, or mortality	In any population, including populations or lifestages that might be at increased risk **(P)**, of interest is the change in risk (incidence/prevalence) of a health effect **(O)** per unit increase **(C)** in ppb of *short- or long-term* ambient concentration of O_3 **(E)**, observed in studies relevant for the health outcome and exposure duration of interest **(S)**. Also of interest is the lowest concentration that produces a measurable change in risk.

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Ecological Studies

Organizing Principle	PECOS Statements
Visible Foliar Injury; Vegetation Growth; Reduced Yield/Quality of Agricultural Crops; Reduced Productivity; Alteration of Below-ground Biogeochemical Cycles	For any individual, population (in the sense of a group of individuals of the same species), species, community, or ecosystem in North America **(P)**; of interest are the effects of ambient ozone exposures, or experimentally elevated ozone concentrations (within an order of magnitude of study-specific ambient or control concentrations) **(E);** when compared to relevant control sites, treatments, or parameters **(C);** on ecological endpoints **(O);** in laboratory, greenhouse, OTC, FACE, field, gradient, or modelling studies **(S)**
Alteration of Terrestrial Water Cycling; Reduced Carbon Sequestration; Alteration of Terrestrial Community Composition; Plant reproduction, phenology or mortality; Insects and other wildlife; Plant-animal signaling	For any individual, population (in the sense of a group of individuals of the same species), species, community, or ecosystem on any continent **(P)** of interest are the effects of ambient ozone exposures, or experimentally elevated ozone concentrations (within an order of magnitude of study-specific ambient or control concentrations) **(E);** when compared to relevant control sites, treatments, or parameters **(C);** on ecological endpoints **(O);** in laboratory, greenhouse, OTC, FACE, field, gradient, or modelling studies **(S)**
Exposure indices; Ozone interactions with abiotic or biotic environmental factors	For any individual, population, species, community, or ecosystem (**P**) of interest are the effects of ozone in dose-response relationships, exposure indices, or in interaction with other environmental factors (e.g., carbon dioxide, nitrogen, temperature, water availability) **(E);** when compared to relevant control sites, treatments, or parameters **(C);** on endpoints in North America (yield and quality of agricultural crops, foliar injury, vegetation growth and productivity, or below-ground biogeochemical cycling), or global-scope endpoints (terrestrial water cycling, carbon sequestration, terrestrial community composition, plant reproduction, phenology and mortality, plant-animal signaling, and invertebrate and vertebrate responses) (**O);** in laboratory, greenhouse, OTC, FACE, field, gradient, or modelling studies **(S)**
Sub-organismal effects of ozone	Ozone effects on sub-organismal endpoints such as gene expression, molecular or chemical composition, or physiological processes for any multi-cellular organism (plant, invertebrate, vertebrate); as well as on plant volatile chemical emissions and plant-plant signaling were not specifically reviewed.

Effects of Tropospheric Ozone on Climate

Effect on Climate	Population, Exposure, Comparison, Outcome, Study Design (PECOS) Statements
Changes in radiative forcing (RF)	Among evaluations of radiative forcing at the regional, continental, and/or global scale **(P)**, of interest is the radiative forcing **(O)** resulting from a given change in tropospheric O_3 concentration **(E)** compared to relevant baseline or unperturbed scenarios/conditions **(C)** in observational or modelling studies **(S)**.
Changes in climate (e.g., surface temperature, hydrological cycle)	Among evaluations of climate effects at the regional, continental, and/or global scale **(P)**, of interest are the subsequent climate effects (via radiative forcing) **(O)** resulting from a given change in tropospheric O_3 concentration **(E)** compared to relevant baseline or unperturbed scenarios/conditions **(C)** in observational or modelling studies **(S)**.
Changes in climate mechanisms and feedbacks	Among evaluations of related mechanisms or feedbacks at the regional, continental, and/or global scale **(P)**, of interest are the mechanisms, feedbacks, and/or copollutants that influence the radiative forcing and/or climate effects **(O)** resulting from a given change in tropospheric O_3 concentration **(E)** compared to relevant baseline or unperturbed scenarios/conditions **(C)** in observational or modelling studies **(S)**.